

12-18-06

TFW 1617



Attorney's Docket No. 007157/239838

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Stein *et al.* Confirmation No.: 5877  
Appl. No.: 09/973,375 Group Art Unit: 1617  
Filed: October 9, 2001 Examiner: Kantamneni, S.  
For: METHODS FOR THE TREATMENT OF A  
TRAUMATIC CENTRAL NERVOUS SYSTEM INJURY

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. § 1.97(c)**

Sir:

Attached is a list of documents on form PTO-1449 along with a copy of any cited foreign patent documents and non-patent literature document in accordance with 37 CFR 1.98(a)(2). Also enclosed is a translation or a concise explanation of each non-English language document.

It is requested that the Examiner consider these documents and officially make them of record in accordance with the provisions of 37 C.F.R. § 1.97 and Section 609 of the MPEP: By identifying the listed documents, Applicant in no way makes any admission as to the prior art status of the listed documents, but is instead identifying the listed documents for the sake of full disclosure.

This Supplemental Information Disclosure Statement is submitted in accordance with 37 C.F.R. § 1.97(c), before final Office Action or Allowance, whichever is earlier.

In accordance with the requirements of 37 C.F.R. § 1.97(c), the following statement as specified in 37 C.F.R. § 1.97(e) is made:

Some items of information contained in this statement were first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this statement. In this regard, Applicants note that the

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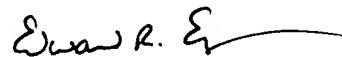
Filed: October 9, 2001

Page 2

communication from the foreign patent office was not received by any individual designated by 37 CFR 1.56(c) more than thirty (30) days prior to the filing of this Information Disclosure Statement.

A check for the \$180.00 fee specified in 37 C.F.R. § 1.17(p) is enclosed. The Commissioner is authorized to charge any additional fee, or credit any refund, to our Deposit Account No. 16-0605.

Respectfully submitted,



Edward R. Ergenzinger  
Registration No. 47,549

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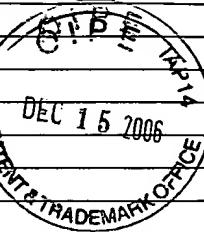
Date of Deposit: December 15, 2006

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to:

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Karyn Grimm

<p>Substitute for form 1449/PTO (Revised 07/2005)</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i></p>			<b>Complete if Known</b>		
			Application Number	09/973,375	
			Filing Date	October 9, 2001	
			First Named Inventor	Stein	
			Group Art Unit	1617	
			Examiner Name	Kantamneni, S.	
Sheet	1	of	2	Attorney Docket Number	007157/239838



<b>U. S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No.	Document Number Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear
	57	US-6,114,388	09-05-2000	Geffard	

<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No.	Foreign Patent Document Country Code - Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	58	WO 02/30409 A2	04-18-2002	Stein and Hoffman	
	59	WO 98/50042	11-12-1998	Kagan <i>et al.</i>	

<b>OTHER DOCUMENTS</b>					
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			English Language Translation Attached
	60	ALLOLIO, B., <i>et al.</i> , "High-Dose Progesterone Infusion in Healthy Males: Evidence Against Antiglucocorticoid Activity of Progesterone," <i>European J. Endocrin.</i> , 1995, pp. 696-700, Vol. 133.			
	61	CHEN, J., <i>et al.</i> , "Neuroprotective Effects of Progesterone After Transient Middle Cerebral Artery Occlusion," <i>J. Neurol. Sci.</i> , 1999, pp. 24-30, Vol. 171.			
	62	CUTLER, S., <i>et al.</i> , "Tapered Progesterone Withdrawal Enhances Behavioral and Molecular Recovery After Traumatic Brain Injury," <i>Experimental Neurology</i> , 2005, pp. 423-429, Vol. 195, Elsevier, Inc.			
	63	CUTLER, S., <i>et al.</i> , "Tapered Progesterone Withdrawal Promotes Long-Term Recovery Following Brain Trauma," <i>Experimental Neurology</i> , 2006, pp. 378-385, Vol. 200, Elsevier, Inc.			
	64	DJEBAILI, M., <i>et al.</i> , "Allopregnanolone and Progesterone Decrease Cell Death and Cognitive Deficits After a Contusion of the Rat Pre-Frontal Cortex," <i>Neuroscience</i> , 2004, pp. 349-359, Vol. 123.			
	65	DJEBAILI, M., <i>et al.</i> , "The Neurosteroids Progesterone and Allopregnanolone Reduce Cell Death, Gliosis, and Functional Deficits After Traumatic Brain Injury in Rats," <i>J. Neurotrauma</i> , 2005 pp. 106-118, Vol. 2.			
	66	GOSS, C., <i>et al.</i> , "Behavioral Effects and Anatomic Correlates After Brain Injury: A Progesterone Dose—Response Study," <i>Pharmacology, Biochemistry and Behavior</i> , 2003, pp. 231-242, Vol. 76, Elsevier, Inc.			

Examiner Signature		Date Considered	
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449/PTO (Revised 07/2005)				Complete if Known	
				Application Number	09/973,375
				Filing Date	October 9, 2001
				First Named Inventor	Stein
				Group Art Unit	1617
				Examiner Name	Kantamneni, S.
Sheet	2	of	2	Attorney Docket Number	007157/239838

OTHER DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	67	GROSSMAN, K., <i>et al.</i> , "Effects of Progesterone on the Inflammatory Response to Brain Injury in the Rat," <i>Brain Res.</i> , 2004, pp. 29-39, Vol. 1008.		
	68	HE, J., <i>et al.</i> , "Allopregnanolone Facilitates Spatial Learning After Traumatic Brain Injury," <i>Soc. Neurosci. Abstr.</i> , 2000, 26: 2296 (862.4).		
	69	HOFFMAN, S., <i>et al.</i> , "Allopregnanolone Reduces Edema After Controlled Cortical Impact Injury in Rats," <i>Soc. Neurosci. Abstr.</i> , 2000, 26: 967 (E30).		
	70	MICHAELS, E., "Cognitive Rehabilitation Advanced by Multifaceted Research, Conference Told," <i>Can. Med. Assoc. J.</i> , 1995, pp. 465-467, Vol. 153.		
	71	ROOF, R.L. and M.E. FRITTS, "Progesterone Metabolites May Mediate Its Neuroprotective Effects After Traumatic Brain Injury," <i>J. Neurotrauma</i> , 1997, pp. 760 Vol. 14(12).		
	72	ROOF, R.L. and E.D. HALL, "Gender Differences in Acute CNS Trauma and Stroke: Neuro-protective Effects of Estrogen and Progesterone," <i>J. Neurotrauma</i> , 2000 pp. 367-388, Vol. 17.		
	73	SHEAR, D., <i>et al.</i> , "Progesterone Protects Against Necrotic Damage and Behavioral Abnormalities Caused by Traumatic Brain Injury," <i>Exp. Neurol.</i> , 2002, pp. 59-67, Vol. 178.		
	74	TAUBØLL, E., and S. LINDSTROM, "The Effect of Progesterone and its Metabolite 5 $\alpha$ -pregnan-3 $\alpha$ -ol-20-one on Focal Epileptic Seizures in the Cat's Visual Vortex in vivo," <i>Epilepsy Research</i> , 1993, pp. 17-30, Vol. 14.		
	75	WRIGHT, D., <i>et al.</i> , "Serum Progesterone Levels Correlate with Decreased Cerebral Edema After Traumatic Brain Injury in Male Rats," <i>J. Neurotrauma</i> , 2001, pp. 901-909, Vol. 18.		

Examiner Signature		Date Considered	
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.